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Please find below and/or attached an Office communication concerning this application or proceeding.

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/897,295
Filing Date: June 29, 2001
Appellant(s): BOYLE ET AL.

MAILED
OCT 24 2007
GROUP 3700

Thomas H. Majcher
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 6/14/07 appealing from the Office action
mailed 09/11/06.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,544,279	HOPKINS et.al.	04/08/2003
6,123,715	AMPLATZ	9-2000
6,517,765	KELLEY	2-2003

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-13, 20-26, 41-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation of "...non-woven reinforcing member..." which was not previously presented in the originally filed specification constitutes new matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 3-13, 20-26, and 41-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hopkins et.al. (6,544,279) in view of Amplatz (6,123,715) and Kelley (6,517,765).

Hopkins in a restraining device discloses a restraining sheath having an expandable housing portion (594) adapted to receive and maintain the self-expanding medical device (588) in a collapsed condition on the delivery device, the expandable housing portion being adapted to move between a contracted position (Fig. 23A) and an expanded position (Fig. 23B), the housing portion having sufficient column strength to maintain the self-expanding medical device (588) in its collapsed condition on its delivery device, wherein the expandable housing portion (594) is made primarily from an elastic material which is movable between the contracted position and expanded position. With respect to the limitation of the reinforcing member being non-woven, Hopkins does not teach a non-woven. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the reinforcing member be a non-woven, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design consideration. Applicant has not disclosed that having the reinforcing member being a non-woven provides an advantage, is used for a particular purpose, or solves any stated problem. One of ordinary skill in the art furthermore would have expected Applicant's invention to perform equally well with other materials, which provide elastic

properties because the housing portion would still be able to expand. Therefore, it would have been an obvious matter of design consideration to modify Hopkins/Amplatz to obtain the invention as specified in claim 3 with the reinforcing member being a non-woven

The difference between Hopkins and claim 3 is a reinforcing member associated therewith which provides additional column strength to the housing portion but does not interfere with the expansion or contraction of the housing portion.

Amplatz in an intravascular occlusion device teaches the use of tubular braids in medical devices providing reinforcing means to the wall of a guiding catheter, which may be adjusted as desired for a particular application by the pitch and pick of the fabric (Col. 3, lines 39-57; Col. 4, lines 11-65). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the expandable housing portion of Hopkins to employ any well-known tubular braids doing so would have provided a means to reinforce the expandable housing portion. Further the teachings of Kelley teach the use of braids in varying braid pick counts vary the flexibility of the tubing (Col. 1, lines 40-67 and Col. 2, lines 1-15). Based on a standard dictionary definition of "flexible, Capable of being bent or flexed; capable of withstanding stress without structural injury: Pliable. "pliable" meaning, easily bent or shaped: Malleable, capable of being shaped or formed. Therefore, based on the teachings of braids of Kelley, the tubular braids of Amplatz could be adjusted to allow for expansion of the housing portion and therefore, would not interfere with the expansion of the housing portion, as one of ordinary skill in the art would know.

With respect to claim 4, Amplatz does not teach a plurality of reinforcing members. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have a plurality of reinforcing members, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960). With respect to the non-woven note rejection of claim 3 above.

With respect to claim 5, Amplatz does not teach the reinforcing member extending substantially along the length of the expandable housing portion. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the reinforcing member extending substantially along the length of the expandable housing portion, since it has been held that rearranging parts of an invention involves only routine skill in the art and applicant has not disclosed that having the reinforcing members extending substantially along the length of the expandable housing portion provides an advantage or solves a particular problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the reinforcing member positioned in any other arrangement of the housing portion because the housing portion would still be expandable. Therefore, it would have been an obvious matter of design consideration to modify Hopkin/Ampatz to obtain the invention as specified in claim 5.

With respect to claim 6, Amplatz teaches the reinforcing members are elongated bar-like members made from a material having a high stiffness (Col. 4, lines 11-65).

With respect to claim 7, Hopkins does not specifically disclose the elastic material selected from the group of materials, which includes silicone, polyurethane, polyisoprene, and lower durometer PEBA. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the elastic material selected from the group of materials which includes silicone, polyurethane, polyisoprene, and lower durometer PEBA, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design consideration. Applicant has not disclosed that having the elastic member selected from the group of materials, which includes silicone, polyurethane, polyisoprene, and lower durometer PEBA provides an advantage, is used for a particular purpose, or solves any stated problem. One of ordinary skill in the art furthermore would have expected Applicant's invention to perform equally well with other materials, which provide elastic properties because the housing portion would still be able to expand. Therefore, it would have been an obvious matter of design consideration to modify Hopkins/Amplatz to obtain the invention as specified in claim 7.

With respect to claim 8, note rejection of claim 7 above.

With respect to claim 9, Hopkins/Amplatz do not disclose/teach the reinforcing members loaded with a material having high radiopacity. However, Hopkins does disclose the use of radipaque bands (596, 598) providing a means so that positions of the bands relative to one another may be accurately determined. It would have been obvious to one of ordinary skill in the art to provide the reinforcing members with a

material having high radiopacity doing so would have provided a means to locate the reinforcing members relative to other structures while in use as disclosed by Hopkins and the use of radiopaque bands.

With respect to claim 10, note rejection of claim 7 above.

With respect to claims 11-13, note rejection of claim 5 above.

With respect to claim 20, Hopkins discloses an expandable housing portion (594) that includes a low expansion section with at least one expansion member (590) disposed within the low expansion section to provide the elasticity needed to move the housing portion between the contracted position and expanded position. ("low expansion section" is being considered by the examiner as a relative phrase, which the specification does not clearly define as to what constitutes a "low expansion section"). Also based on the teachings of Amplatz and the pitch and pick of the braid being adjusted as desired for a particular application it would have been obvious to one of ordinary skill in the art to have low expansion sections.

With respect to claim 21, note rejection of claim 4 above.

With respect to claim 22, note rejection of claim 9 above.

With respect to claims 23 and 24, note rejection of claim 7 above.

With respect to claim 25, note rejection of claim 4 above.

With respect to claim 26, Amplatz teaches reinforcing members (Col. 3, lines 39-57) which are fully capable of preventing the low expansion sections from tearing as the expandable housing portion expands from the contracted position to the expanded

position because the reinforcing members provide strength which allowing for expansion.

With respect to claim 41, note rejection of claim 3 above.

With respect to claim 42, note rejection of claim 4 above.

With respect to claims 43, 49, and 50, note rejection of claim 5 above.

With respect to claim 44, note rejection of claim 6 above.

With respect to claims 45, 46, and 48, note rejection of claim 7 above.

With respect to claim 47, note rejection of claim 9 above.

With respect to claim 51, the reinforcing members of Amplatz are fully capable of helping to bias the expandable housing portion in the contracted position based on the pitch and pick used (Col. 4, lines 10-65).

(10) Response to Argument

Appellant argues that Hopkins does not disclose a housing portion made primarily from an elastic material which is movable between a contracted position and expanded positions (note Col. 23, lines 5-49) Appellant shows Figures 23A, 23B, however based upon the material comprising an elastomeric material, such as latex, rubber or a synthetic variant, the housing is inherently able to expand and contract. Appellant further argues that Hawkins (the examiner assumes Appellant has a typographical error) does fails to disclose the use or need for any reinforcing member with its housing and that if the end region 594 did not possess sufficient column strength, the expander 590 would crush the tubing longitudinally as the expander 590 is drawn into the end region. Amplatz was brought in for the teaching of tubular braids for

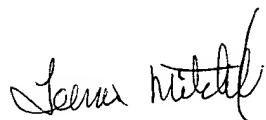
providng reinforcing means to the wall of a guiding catheter, which can be adjusted as desired for a particular application. Therefore based upon the intended use of the device the tubular braids would be adjusted to meet the needs of the specific application by the pitch and pick of the fabric (Col. 3, lines 39-57; Col. 4, lines 11-65; of Amplatz). Further the teachings of Kelley teach the use of braids in varying braid pick counts vary the flexibility of the tubing (Col. 1, lines 40-67 and Col. 2, lines 1-15). Based on a standard dictionary definition of "flexible, Capable of being bent or flexed; capable of withstanding stress without structural injury: Pliable. "pliable" meaning, easily bent or shaped: Malleable, capable of being shaped or formed. Therefore, based on the teachings of braids of Kelley, the tubular braids of Amplatz could be adjusted to allow for expansion of the housing portion and therefore, would not interfere with the expansion of the housing portion, as one of ordinary skill in the art would know. Based upon the teaches of Amplatz of a catheter and the braids used for providing reinforcing means to the wall which can be adjusted as desired and Hopkins is a catheter device one of ordinary skill would look to Amplatz for the teaching of reinforcing means for the wall which can be adjusted to meet specific needs of specific applications.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,



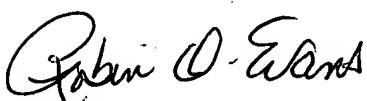
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October 4, 2007

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